K123541

SIEMENS

APR 0 2 2013

510(K) SUMMARY
FOR
SYNGO.CT NEURO PERFUSION

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: November 14, 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**
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   Malvern, PA 19355-1406
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2. **Device Name and Classification**

Product Name:	syngo.CT Neuro Perfusion
Propriety Trade Name:	syngo.CT Neuro Perfusion
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

3. **Substantial Equivalence:**
Siemens syngo.CT Neuro Perfusion post processing software package is substantially equivalent to the following medical devices in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
syngo® Volume Perfusion CT-Neuro	K073238	01/03/2008

4. **Device Description:**
The syngo.CT Neuro Perfusion software allows the quantitative evaluation of dynamic CT data of the brain acquired during the injection of a compact bolus of iodinated contrast material. It mainly aids in the early differential diagnosis of acute ischemic stroke. Blood-brain-barrier (BBB) imaging also supports the diagnostic assessment of brain tumors.

By providing images of e.g. cerebral blood flow (CBF), cerebral blood volume (CBV), time to peak (TTP), and Mean Transit Time (MTT) from one set of dynamic CT images or volumes, *syngo*.CT Neuro Perfusion allows a quick and reliable assessment of the type and extent of cerebral perfusion disturbances. The underlying approaches have been validated in extensive clinical studies and have been in routine clinical use for more than 10 years.

The current syngo.CT Neuro Perfusion implementation allows simultaneous multi-slice processing and supports the workflow requirements in a stroke workflow. The availability of flow extraction product imaging extends the option to the diagnosis of brain tumors.

5. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**
syngo.CT Neuro Perfusion software package is designed to evaluate areas of brain perfusion and visualize blood brain barrier disturbances. Syngo. CT Neuro Perfusion has similar intended use as the predicate syngo® Volume Perfusion-CT Neuro (K073238, clearance date 01/03/2008). syngo.CT Neuro Perfusion is designed to be operated on syngo.via platform in a single or multi user environment. New or modified features provided with syngo.CT Neuro Perfusion are provided in the device description.

6. **Nonclinical Testing:**
syngo.CT Neuro Perfusion is designed to fulfill the requirements of following standards.

- IEC 60601-1-6 : 2006; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: 2008DICOM conformity is fully covered by syngo.via implementations.

Non clinical tests were conducted for syngo.CT Neuro Perfusion software package during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

7. Indications for Use:

The syngo.CT Neuro Perfusion software package is designed to evaluate areas of brain perfusion. The software processes images or volumes that were reconstructed from continuously acquired CT data after the injection of contrast media.

It generates the following result volumes:

- Cerebral blood flow (CBF)
- Cerebral blood volume (CBV)
- Local bolus timing (time to start (TTS), time to peak (TTP), time to drain (TTD))
- Mean transit time (MTT)
- Transit time to the center of the IRF (TMax)
- Flow extraction product (permeability)
- Temporal MIP
- Temporal Average
- Baseline Volume
- Modified dynamic input data

The software also allows the calculation of mirrored regions or volumes of interest and the visual inspection of time attenuation curves. One clinical application is to visualize the apparent blood perfusion and the parameter mismatch in brain tissue affected by acute stroke.
Areas of decreased perfusion appear as areas of changed signal intensity:

- Lower signal intensity for CBF and CBV
- Higher signal intensity for TTP, TTD, MTT, and TMax

A second application is to visualize blood brain barrier disturbances by modeling extra-vascular leakage of blood into the interstitial space. This additional capability may improve the differential diagnosis of brain tumors and be helpful in therapy monitoring.

8. **General Safety and Effectiveness Concerns:**
The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

9. **Conclusion as to substantial Equivalence:**
In summary, Siemens is of the opinion that the syngo.CT Neuro Perfusion software package does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 2, 2013

Siemens Medical Systems, Inc.
% Ms. Kimberly Mangum
Technical Specialist, Regulatory Submissions
51 Valley Stream Parkway, G-01
MALVERN PA 19355

Re: K123541
Trade/Device Name: syngo.CT Neuro Perfusion
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 8, 2013
Received: March 13, 2013

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K123541

Device Name: ***syngo.CT Neuro Perfusion***

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2013.04.02
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(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123541